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DOCKET NO.: ORTU-0007

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In Re Application of:**

**Robert A. Raffa, Jeffrey Vaught**

**Confirmation No.: 2441**

**Application No.: 10/761,096**

**Group Art Unit: 1614**

**Filing Date: January 20, 2004**

**Examiner: Jones Dwayne C**

**For: COMPOSITIONS COMPRISING A TRAMADOL MATERIAL AND  
ACETOMINOPHEN AND ITS USE**

**EXPRESS MAIL LABEL NO: EL 998522048 US  
DATE OF DEPOSIT: September 12, 2005**

**EL 998522048US**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☐ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or

before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☒ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.116 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☒ The fee of \$180.00 as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).

- ☒ Copies of reference numbers **258 thru 269** listed on the attached Form PTO-1449 are enclosed herewith.

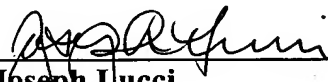
- ☐ Copies of reference numbers - on the attached Form PTO 1449 are not required to be submitted pursuant to 37 CFR § 1.98(a)(2)(i).

- ☐ Copies of references - are not being submitted because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application number , filed for which a claim for priority under 35 U.S.C. § 120 has been made in the instant application.

There are no listed references which are not in the English language.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

Date: **September 12, 2005**

  
**Joseph Lucci**  
Registration No. 33,307

**WOODCOCK WASHBURN LLP**  
One Liberty Place - 46th Floor  
Philadelphia, PA 19103  
Telephone: (215) 568-3100  
Facsimile: (215) 568-3439



<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. <b>ORTU-0007</b>	Application No. <b>10/761,096</b>
		Applicant <b>Robert A. Raffa, et al.</b>	
		Filing Date <b>January 20, 2004</b>	Group <b>1614</b>
		Confirmation No. <b>2441</b>	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	258	In the United States District Court for the District of New Jersey, <b>Civil Action No. 02-2707(JCL)</b> , Ortho-McNeil Pharmaceutical, Inc., v. Kali Laboratories, Inc.: First Amended Complaint for Patent Infringement, <b>July 27, 2005</b>	
	259	In the United States District Court for the District of New Jersey, <b>Civil Action No. 02-2707(JCL)</b> , Ortho-McNeil Pharmaceutical, Inc., v. Kali Laboratories, Inc.: Defendant Kali Laboratories, Inc.'s Second Amended Answer, Counterclaim, and Jury Demand and Defendants Par Pharmaceutical Companies, Inc.'s and Par Pharmaceutical, Inc.'s Answer, Counterclaim, and Jury Demand, <b>August 25, 2005</b>	
	260	In the United States District Court for the District of New Jersey, <b>Civil Action No. 04-886(HAA)</b> , Ortho-McNeil Pharmaceutical, Inc., v. Teva Pharmaceutical Industries Ltd., Videotape Deposition of Eric Smith, Ph.D., <b>May 13, 2005</b>	
	261	In the United States District Court for the District of New Jersey, <b>Civil Action No. 04-886(HAA)</b> , Ortho-McNeil Pharmaceutical, Inc., v. Teva Pharmaceutical Industries Ltd., Deposition of Dr. David Schoenfeld, <b>May 17, 2005</b>	
	262	In the United States District Court for the District of New Jersey, <b>Civil Action No. 04-886(HAA)</b> , Ortho-McNeil Pharmaceutical, Inc., v. Teva Pharmaceutical Industries Ltd., Deposition of Donald Stanski, M.D., <b>May 27, 2005 (REDACTED)</b>	
	263	In the United States District Court for the District of New Jersey, <b>Civil Action No. 04-886(HAA)</b> , Ortho-McNeil Pharmaceutical, Inc., v. Teva Pharmaceutical Industries Ltd., Deposition of Dr. Gilbert Fanciullo, <b>June 14, 2005</b>	
	264	In the United States District Court for the Eastern District of Michigan, <b>Civil Action No. 2:04CV73698</b> , Ortho-McNeil Pharmaceutical, Inc., v. Caraco Pharmaceutical Laboratories, Ltd., Caraco's Supplemental Response to Plaintiff's First Set of Interrogatories, <b>June 14, 2005, REDACTED</b>	
	265	In the United States District Court for the Eastern District of Michigan, <b>Civil Action No. 2:04CV73698</b> , Ortho-McNeil Pharmaceutical, Inc., v. Caraco Pharmaceutical Laboratories, Ltd., Caraco's Second Supplemental Response to Plaintiff's First Set of Interrogatories, <b>June 24, 2005</b>	
	266	In the United States District Court for the Eastern District of Michigan, <b>Civil Action No. 2:04CV73698</b> , Ortho-McNeil Pharmaceutical, Inc., v. Caraco Pharmaceutical Laboratories, Ltd., Caraco's Motion for Summary Judgment of Non-Infringement, <b>August 5, 2005, REDACTED</b>	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	

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		Applicant <b>Robert A. Raffa, et al.</b>	
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<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	<b>267</b>	In the United States District Court for the Eastern District of Michigan, <b>Civil Action No. 2:04CV73698</b> , Ortho-McNeil Pharmaceutical, Inc., v. Caraco Pharmaceutical Laboratories, Ltd., Expert Report of Donald R. Stanski, M.D. <b>August 5, 2005</b> , <b>REDACTED</b>	
	<b>268</b>	In the United States District Court for the Eastern District of Michigan, <b>Civil Action No. 2:04CV73698</b> , Ortho-McNeil Pharmaceutical, Inc., v. Caraco Pharmaceutical Laboratories, Ltd., Expert Report of Eric P. Smith, Ph.D., <b>August 8, 2005</b>	
	<b>269</b>	In the United States District Court for the Eastern District of Michigan, <b>Civil Action No. 2:04CV73698</b> , Ortho-McNeil Pharmaceutical, Inc., v. Caraco Pharmaceutical Laboratories, Ltd., Ortho-McNeil's Opposition to Caraco's Motion for Summary Judgment of Non-Infringement, <b>August 29, 2005</b> , <b>REDACTED</b>	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	